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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,265	06/27/2003	Ralph F. Kalies	036806.00434	8330

7590 03/05/2009

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EXAMINER	
RANGREJ, SHEETAL	

ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
03/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,265	KALIES, RALPH F.	
	Examiner	**Art Unit**	
	SHEETAL R. RANGREJ	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _11 December 2008_.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-12 and 14_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-12 and 14_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Prosecution History Summary

1. Claim 1 and 14 are amended.

2. Claim 13 is cancelled.

3. Claims 1-12 and 14 are pending.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "<u>wherein the second payment and the third payment are funded by the first payment such that prescription benefits plan requires 100% subscriber co-pay less the portion of the cost of the prescription for which the participating pharmacy is responsible</u>." It is unclear from the claim language how if the first payment is minus the service fee, it could also fund the third payment, which is a service fee. Furthermore, the claim language is indefinite in the terminology of "requires 100% subscriber co-pay less the portion of the cost of the prescription." It is unclear from the claim language how a portion of the cost of the prescription is deducted if plan requires 100% subscriber co-pay. For examination purposes,

Examiner interprets the claim language to mean wherein the second and third payment is paid by the manager and the subscriber pays the manager.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 3-4, 6, 10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oscar et al. (U.S. Publication No. 2001/0037216) in view of Ullman (U.S. Publication no. 2002/0002495) and further in view of Freeman, Jr. et al. (U.S. Patent No. 6,012,035).

9. As per claim 1, Oscar teaches a method of providing prescription benefits to subscribers under a subscriber co-pay plan, comprising the steps of:

a) identifying a sponsor for a prescription benefits plan **(Oscar: para. 0049, 1-4)**;

b) designing the prescription benefits plan, to include a formulary of preferred medications, and to define prescription medications that are covered by the prescription benefits plan, a portion of a cost of a prescription that a subscriber is responsible for, an amount of co-payment to be tendered by the subscriber at time of dispensing, and a portion of a cost of the prescription for which a participating pharmacy is responsible **(Oscar: para. 63-64)**;

c) identifying at least one pharmacy that **(Oscar: para. 50, 23)**:

i) participates in the prescription benefits plan **(Oscar: para. 50, 23)**. The examiner interprets that identifying a pharmacy with the benefits plan means the pharmacy participates in the prescription benefits plan.

ii) receives prescriptions for medication and prescription benefit claims from subscribers, and iii) fulfills the prescriptions for a predetermined price; **(Oscar: para. 51)**. The examiner interprets that seeing a list of the drugs dispensed and the cost means that the prescriptions were received and fulfilled.

e) enrolling each eligible subscriber who wishes to participate in the prescription benefits plan **(Oscar: para. 50, 1-3)**;

f) generating an eligibility profile for each subscriber **(Oscar: figure 8; para. 50)**. The examiner interprets the summary displayed to be the same as an eligibility profile;

Oscar does not teach: d) identifying at least one eligible subscriber having a valid credit or debit account with a creditor or institution and wishing to participate in the prescription benefits plan; g) establishing a prescription benefits manager to administer the prescription benefits plan; and h) establishing a prescription claims processor that: i) receives claims for prescription benefits from a participating pharmacy; ii) adjudicates the claims in accordance with the subscriber's eligibility profile;**;** iii) upon approval of a claim, charges the subscriber's credit account for accepted claims, the amount of the charge being equal to the price of the prescription minus a predetermined co-payment which is tendered by the subscriber to the pharmacy at the time of fulfilling the prescription; i) <u>making</u> first payment, by the creditor to the prescription benefits manager, the first payment being equal to the amount charged to the subscriber's account

minus a first predetermined service fee to be retained by the creditor; j) making second payment, by the prescription benefits manager to the pharmacy, the second payment being equal to a predetermined portion of the prescription price; and k) making third payment, by the prescription benefits manager to the claims processor, the third payment being equal to a predetermined service fee, wherein the second payment and the third payment are funded by the first payment such that prescription benefits plan requires 100% subscriber co-pay less the portion of the cost of the prescription for which the participating pharmacy is responsible.

Ullman teaches the following:

d) identifying at least one eligible subscriber having a valid credit or debit account with a creditor or institution and wishing to participate in the prescription benefits plan **(Ullman: figure 2, references S3 and S6-S7; para. 0007)**;

g) establishing a prescription benefits manager to administer the prescription benefits plan **(Ullman: para. 18)**; and

h) establishing a prescription claims processor **(Ullman: para. 20)** that:

i) receives claims for prescription benefits from a participating pharmacy; ii) adjudicates the claims in accordance with the subscriber's eligibility profile; **(Ullman: para. 22-25);**

iii) upon approval of a claim, charges the subscriber's credit account for accepted claims, the amount of the charge being equal to the price of the prescription minus a predetermined co-payment which is tendered by the subscriber to the pharmacy at the time of fulfilling the prescription **(Ullman: para. 31)**;

j) making second payment, by the prescription benefits manager to the pharmacy, the second payment being equal to a predetermined portion of the prescription price **(Ullman: para. 25 and 32)**; and

k) making third payment, by the prescription benefits manager to the claims processor, the third payment being equal to a predetermined service fee, wherein the second payment and the third payment are funded by the first payment such that prescription benefits plan requires 100% subscriber co-pay less the portion of the cost of the prescription for which the participating pharmacy is responsible **(Ullman: para. 0017 and para. 0012)**.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oscar and Ullman. One of ordinary skill would have been motivated to combine these teachings because healthcare costs have risen dramatically; hence most health care is delivered through employer sponsored health care plans. Pharmacy Benefit Managers (PBMs) are used to process claims for prescription drug benefits and attempt to control costs. PBMs submit claims documentation to the claims processor to collect the remaining cost for the dispensed drug. **(Oscar: para. 5-9)**

Ullman does not teach i) making first payment, by the creditor to the prescription benefits manager, the first payment being equal to the amount charged to the subscriber's account minus a first predetermined service fee to be retained by the creditor.

Freeman teaches i) making first payment, by the creditor to the prescription benefits manager, the first payment being equal to the amount charged to the subscriber's account minus a first predetermined service fee to be retained by the creditor **(Freeman: col. 2, 38-41)**.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oscar in view of Ullman with Freeman. One of ordinary skill would have been motivated to combine these teachings because individuals receive medical services through coverage by third party payor with the balance payment remaining the responsibility of the patient. At other times, claims are submitted by patient or by the provider who then pays the provider, patient, or both. There are many inefficiencies and inequalities inherent in this disjointed health care system and procedure. **(Freeman: col. 1, 26-40)**

10. As per claim 3, the method of claim 1 is as described. Oscar and Freeman do not teach further comprising the steps of: a) imprinting subscriber information onto identification cards; and b) distributing the identification cards to the subscribers.

Ullman teaches further comprising the steps of:

a) imprinting subscriber information onto identification cards **(Ullman: para. 7; para. 0032, 13-15)**; and

b) distributing the identification cards to the subscribers **(Ullman: para. 0032, 13-23)**.

The motivation to combine Oscar and Ullman is as same as the reasons described for claim 1.

11. As per claim 4, the method of claim 1 is as described. Oscar further teaches wherein the amount of the co-payment is determined by the medication's inclusion, exclusion or ranking in the formulary **(Oscar: para. 51, 6-21)**.

12. As per claim 6, the method of claim 1 is as described. Oscar further teaches wherein the prescription benefits manager further generates reports relating to subscriber prescription claims **(Oscar: para. 55)**.

13. As per claim 10, the method of claim 1 is as described. Oscar further teaches wherein an electronic means for telecommunication is used to link at least two of the participants comprising the subscriber, the prescription benefits plan sponsor, the pharmacy the prescription benefits manager, the claims processor and the creditor or institution **(Oscar: para. 50)**.

14. As per claim 12, the method of claim 1 is as described. Oscar and Ullman do not teach wherein the first payment is in the form of a credit to an account which is periodically paid out to the prescription benefits manager. The examiner interprets that since the bill is provided to the patient, the payment was in the form of a credit.

Freeman teaches wherein the first payment is in the form of a credit to an account which is periodically paid out to the prescription benefits manager **(Freeman: col. 2, 38-50)**. The examiner interprets that since the bill is provided to the patient, the payment was in the form of a credit.

The motivation to combine Oscar in view Ullman with Freeman is as same as the reasons described for claim 1.

15. As per claim 13, the method of claim 1 is as described. Oscar and Freeman do not teach wherein the sponsor for the prescription benefits plan is self-funded.

Ullman teaches wherein the sponsor for the prescription benefits plan is self-funded **(Ullman: para. 16)**.

16. As per claim 14, the method of claim 1 is as described. Oscar and Freeman do not teach wherein the sponsor reimburses the subscriber in an amount related to the subscriber's participation in formulary-determined preferences **(Ullman: para. 25, 4-9)**.

Ullman teaches wherein the sponsor reimburses the subscriber in an amount related to the subscriber's participation in formulary-determined preferences **(Ullman: para. 25, 4-9)**.

Regarding claims 13-14, the motivation to combine Oscar and Ullman is as same as the reasons described for claim 1.

17. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oscar et al. (U.S. Publication No. 2001/0037216) in view of Ullman (U.S. Publication no. 2002/0002495) and further in view of Freeman, Jr. et al. (U.S. Patent No. 6,012,035) and Judge (U.S. Publication No. 2002/0111832).

18. As per claim 2, the method of claim 1 is as described. Oscar, Ullman and Freeman do not teach wherein the claims processor further: a) performs a drug regimen review prior to approval of a claim; and b) advises the pharmacy of the review results.

Judge teaches wherein the claims processor further: a) performs a drug regimen review prior to approval of a claim; and b) advises the pharmacy of the review results **(Judge: para. 110)**.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oscar in view of Ullman with Freeman and Judge. One of ordinary skill would have been motivated to combine these teachings because it is to improve the quality of care while capping costs **(Judge: para. 0003)**.

19. Claims 5, 7-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oscar et al. (U.S. Publication No. 2001/0037216) in view of Ullman (U.S. Publication no. 2002/0002495) and further in view of Freeman, Jr. et al. (U.S. Patent No. 6,012,035) and Mayaud (U.S. Patent No. 5,845,255).

20. As per claim 5, the method of claim 1 is as described. Oscar, Ullman, and Freeman do not teach wherein the adjudication of claims by the claims processor further comprises the steps of: a) checking the prescription against the formulary; and b) recommending medications to the pharmacy for fulfilling the prescription, the recommendation being determined by formulary preferences.

Mayaud teaches wherein the adjudication of claims by the claims processor further comprises the steps of: a) checking the prescription against the formulary; and b) recommending medications to the pharmacy for fulfilling the prescription, the recommendation being determined by formulary preferences. **(Mayaud: col. 35, 57 to col. 36, 9)**

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oscar in view of Ullman with Freeman and Mayaud. One of ordinary skill would have been motivated to combine these teachings because there is a difficulty in making integrated patient-specific information readily available to prescribing professionals that need information components because they are not centralized but are widely distributed geographically and even when their geographic or electronic locations are known, they are hard to access because of proprietary and liability and patient-confidentiality concerns and because of system, file, or protocol incompatibilities. **(Mayaud: col. 2, 12-20)**

21. As per claim 7, the method of claim 1 is as described. Oscar and Freeman do not teach wherein the prescription benefits manager further: a) identifies at least one market for at least one selected prescription medication, for at least one pharmaceutical company; b) accumulates usage data regarding consumption of the at least one selected prescription medication by the subscribers; c) periodically provides the usage data to the pharmaceutical company; and d) receives an incentive from the pharmaceutical company as a result of an increase in market share for the selected prescription medication among the subscribers.

Ullman does not teach wherein the prescription benefits manager further: a) identifies at least one market for at least one selected prescription medication, for at least one pharmaceutical company; b) accumulates usage data regarding consumption of the at least one selected prescription medication by the subscribers; c) periodically provides the usage data to the pharmaceutical company.

Mayaud teaches wherein the prescription benefits manager further: a) identifies at least one market for at least one selected prescription medication, for at least one pharmaceutical company **(Mayaud: col. 39, 36-43)**; b) accumulates usage data regarding consumption of the at least one selected prescription medication by the subscribers **(Mayaud: col. 39, 55-65)**; c) periodically provides the usage data to the pharmaceutical company **(Mayaud: col. 39, 44-54)**.

Mayaud does not teach d) receives an incentive from the pharmaceutical company as a result of an increase in market share for the selected prescription medication among the subscribers **(Ullman: para. 34)**.

Ullman teaches d) receives an incentive from the pharmaceutical company as a result of an increase in market share for the selected prescription medication among the subscribers **(Ullman: para. 34)**.

The motivation to combine Oscar in view Ullman with Freeman and Mayaud is as same as the reasons described for claim 5. Furthermore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Oscar in view of Ullman with Freeman and Mayaud. One of ordinary skill would have been motivated to combine these teachings because designing advertisements, doing research to define the exact target audience, and choosing where, when, and how to place the advertisements are burdensome. An alternative method of marketing is the issuance of redeemable coupons. However, the management of coupon verification, shuffling, and redemption is also an administrative nightmare. What is needed is an effective consumer rewards program scalable for all merchants in the retail pharmaceutical industry. **(Ullman: para. 3-5)**

22. As per claim 8, the method of claim 7 is as described. Oscar, Freeman, and Mayaud do not teach further comprising the step of sharing at least a portion of the incentive with subscribers who contribute to the increase in market share.

Ullman teaches further comprising the step of sharing at least a portion of the incentive with subscribers who contribute to the increase in market share **(Ullman: para. 34)**.

The motivation to combine Oscar in view Ullman with Freeman and Mayaud is as same as the reasons described for claim 5 and 7.

23. As per claim 9, the method of claim 8 is as described. Oscar, Freeman, and Mayaud do not teach wherein the amount of the incentive shared with a subscriber is related to that subscriber's contribution to the increase in market share **(Ullman: para. 35)**.

Ullman teaches wherein the amount of the incentive shared with a subscriber is related to that subscriber's contribution to the increase in market share **(Ullman: para. 35)**.

The motivation to combine Oscar in view Ullman with Freeman and Mayaud is as same as the reasons described for claim 5 and 7.

As per claim 11, the method of claim 7 is as described. Oscar teaches wherein an electronic means for telecommunication is used to link the pharmaceutical company and the prescription benefits manager **(Oscar: para. 11)**.

Response to Arguments

24. Applicant's arguments filed for claims 1-14 have been fully considered but they are not persuasive.

25. Applicant argues that neither Oscar, Ullman, nor Freeman teach or suggest the amended features of claim 1. Examiner disagrees with the applicant. Ullman teaches an obligor responsible for making payment for the health care services associated with a plan, i.e. 100% subscriber co-pay less the portion of the cost of the prescription.

26. Applicant argues that Oscar does not teach "designing the prescription benefits plan, and to define prescription medications that are covered by the prescription benefits plan, a portion of a cost of a prescription that a subscriber is responsible for, an amount of co-payment to be tendered by the subscriber at time of dispensing, and a portion of a cost of the prescription for which a participating pharmacy is responsible. Examiner disagrees and states that Oscar teaches "designing" the plan in that the consultant module of Oscar is used to analyze and construct pharmacy benefit plans. Consultant can change the proposed levels of co-payments or coinsurance percentage and, can change co-payment amounts of the benefits structure, which is the same as designing a prescription benefits plan.

27. Applicant argues that Judge does not teach or suggest the missing elements that are missing from the combined teachings of Oscar, Ullman, and Freeman. Applicant states that Judge, instead is directed to delivering a pharmaceutical prescription co-pay counselor over an internet protocol network. Applicant further argues that Judge does not teach or suggest applicant's missing elements, including "identifying a sponsor for a prescription benefits plan,"

"designing the prescription benefits plan," and "enrolling each eligible subscriber who wishes to participate in the prescription benefits plan." Applicant disagrees, and states that Oscar, Ullman, Freeman, and Judge together combined teaches the applicant's claimed invention and with the motivation provided above. Furthermore, it is submitted that applicant is arguing against the references individually when a combination of references are used in the rejection.

28. Applicant argues that Mayaud does not regard a method of providing prescription benefits to subscribers under a plan, and, as described with reference Oscar, Ullman, and Freeman, Mayaud does not teach or suggest the missing elements, including applicant's claimed steps of "identifying a sponsor," "designing the prescription benefits plan," and "enrolling each eligible subscriber who wishes to participate in the prescription benefits plan." Examiner disagrees, and states that Oscar, Ullman, Freeman, and Mayaud together combined teaches the applicant's claimed invention and with the motivation provided above.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/S. R. R./
Examiner, Art Unit 3686
March 2, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686